

Attorney Docket No. 6450.000-US  
Serial No. 10/006,601  
Filed: December 4, 2001  
Inventors: Philip Hougaard

#### **REMARKS/ARGUMENTS**

Claims 1-7, 9-20, 22-41, 43-60, 62-66, 68-70 and 72-81 are pending following entry of the amendments to the claims presented herein.

#### **REJECTION OF THE CLAIMS UNDER 35 U.S.C. 101**

The Examiner rejected claims 1-19, 24-40, 45-59, 64-66, 70, 74, and 78-81 under section 101 as being directed to non-statutory subject matter because the claims are directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

In reply, Applicant submits that these rejections are rendered moot by the amendments to claims 1, 24 and 45 presented herein.

#### **REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, SECOND PARAGRAPH**

The Examiner rejected claims 1-81 as being indefinite for the following reasons:

- 1) there is insufficient antecedent basis for the recitation of "the expected degradation rate" in claims 1, 24 and 45;
- 2) there is insufficient antecedent basis for the recitation of "the intermediate position" in claims 1, 24 and 45;
- 3) the phrase "such as" in claims 20, 41, and 60; and
- 4) the preamble of claim 45 is directed to a method of planning a stability study whereas one of the limitations in the body of the claim is directed to conducting a stability study.

In reply, Applicant submits that these rejections are rendered moot by the amendments to claims 1, 20, 24, 41, 45 and 60 presented herein.

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**REJECTION OF THE CLAIMS UNDER 35 U.S.C. 102 (e)(1)**

The Examiner rejected claims 1-2, 10, 20-23 and 64-69 as anticipated by Levinson et al US 2002/0177167.

In reply, Applicant submits that this rejection is rendered moot by the incorporation of the limitation of now cancelled claim 8 into amended claim 1.


Accordingly, in view of the above amendments and remarks, Applicant respectfully submits that the pending claims are now in condition for allowance.

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Please charge any deficiencies or overpayment to Deposit Account No.14-1447.

Respectfully submitted,

Date: December 22, 2004

  
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**23650**

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